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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte STEPHEN SOLOMON, MOSHE SHIKE,
and SAM KLEIN

Appeal 2008-4105
Application 10/702,194
Technology Center 3700

Decided: December 1, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for treating obesity by removing partially digested food from a patient's upper digestive system. We have jurisdiction under 35 U.S.C. § 6(b). We affirm

STATEMENT OF THE CASE

Background

“Surgical procedures present an increasingly common solution for morbidly obese patients” (Spec. 2:3-4). The Specification notes that “[s]urgical procedures include both gastric restrictive operations and malabsorptive operations and will be performed in an estimated 98,000 patients in 2003” (Spec. 2:7-10). The Specification comments that “[t]hese surgical procedures, however, are the most invasive and risky” (Spec. 5:10-12).

The Claims

Claims 17, 18, and 32-34 are on appeal.¹ We will focus on claims 17 and 32, which are representative and read as follows:

17. A method comprising:
 - inserting a tube into a patient such that a proximal end portion of the tube is disposed in the upper digestive system of the patient and a distal end portion of the tube extends externally from the patient;
 - connecting a pump to the distal end portion of the tube;
 - controlling the pump to remove partially digested food from the upper digestive system of the patient through the tube
 - monitoring a volume of the pumped food;
 - ending the pumping when the monitored volume exceeds preset parameters within a given time.
32. A method of treating obesity comprising the steps of:
 - (a) positioning a tube that passes through an obese patient's abdominal wall into an upper digestive system of the obese patient;

¹ Claims 1-15 and 20 were withdrawn in response to the Examiner's restriction requirement.

- (b) allowing the obese patient to ingest food;
 - (c) extracting the food from the upper digestive system of the obese patient through the tube after the obese patient has ingested the food; and
 - (d) repeating steps (b) and (c) until the patient is no longer obese,
- wherein the food that has been extracted in step (c) is not reintroduced into the obese patient.

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Kenneth Joel Shapiro, *Animal Models of Human Psychology*, 113-210 (Hogrefe & Huber) (1998).

The issue

The Examiner rejected claims 17, 18, and 32-34 under 35 U.S.C. § 103(a) as being obvious over Shapiro (Ans. 4-6).

The Examiner argues that the “prior art of Shapiro either teaches explicitly or fairly suggests all of the steps of the claimed method” (*id.* at 8). The Examiner concludes that

Shapiro does not explicitly teach monitoring a volume of the pumped food, however, since the very function of the sham-feeding method taught by Shapiro is to draw out ingested foodstuffs in such a way as to prevent nutrient absorption . . . it would be obvious to one of ordinary skill in the art to modify the method of Shapiro so as to include the step of monitoring a volume of the pumped food.

(*Id.* at 4.) The Examiner also argues that “[w]hile the rat which is the subject of Shapiro’s sham-feeding model may not be obese

upon the first cycle of ingesting foodstuffs, the rat necessarily becomes obese prior to the drawing out of said foodstuffs” (*id.* at 8-9).

Appellants “submit that . . . Shapiro [does not] teach[] or suggest[] the limitations recited in claim 17 of ‘monitoring a volume of pumped food’ and ‘ending the pumping when the monitored volume exceeds preset parameters within a given time’” (App. Br. 9-10). Appellants further argue that “since nothing in Shapiro suggests that bulimia and obesity are the same thing, the fact that they are appear in the same sentence does not establish that they are interchangeable” (*id.* at 10).

In view of these conflicting positions, we frame the obviousness issues before us as follows:

(1) Did the Examiner err in finding that it would have been obvious to an ordinary practitioner to monitor the volume of pumped food in Shapiro?

(2) Did the Examiner err in finding that the treatment of obesity in claims 32-34 would have been obvious over the teachings of Shapiro?

Findings of Fact (FF)

1. Shapiro states that “[a]ny intervention at any level . . . that *increases* food intake is a potential model of obesity and bulimia. But it is also a possible treatment of anorexia. Any intervention at any level that *decreases* food intake is a potential

model of anorexia but also a treatment of obesity and bulimia”
(Shapiro 117).

2. Shapiro teaches a method where “a stainless steel tube (cannula) is sutured into the stomach of an anesthetized rat”
(Shapiro 126).

3. Shapiro teaches that “[a]fter coming out of the muscle wall of the stomach, the tube emerges on the back of the animal, under the shoulder” (Shapiro 126).

4. Shapiro teaches that “[t]his tube can be connected to a syringe to draw out ingested (or, less commonly, to introduce) foodstuffs” (Shapiro 126).

5. Shapiro teaches that “[f]istulae are utilized in sham feeding in such a way that the animal eats or drinks without receiving nutritional benefits” (Shapiro 125).

6. Shapiro teaches a
[R]at “preparation” that can include any or all of the following: intra-gastric cannula to effect sham feeding; intraoral cannula with external leads issuing out of an acrylic headcap and extending into the ceiling of the chamber to allow direct infusion of controlled amounts and concentrations of liquids into the mouth;

(Shapiro 13.)

7. Shapiro teaches that “[w]ith ingested food draining from an open esophageal or gastric fistula, ‘animals sham feeding for the first time increase meal size 3-6 times’” (Shapiro 127).

8. The Examiner found that

[S]ince the very function of the sham-feeding method taught by Shapiro is to draw out ingested foodstuffs in such a way as to prevent nutrient absorption . . . it would be obvious to one of ordinary skill in the art to modify the method of Shapiro so as to include the step of monitoring a volume of the pumped food.

(Ans. 5.)

9. The Examiner found that

[T]he purpose of a preset parameter is to provide a value that sets a boundary on a physical situation, for example the monitored volume of food required to prevent nutrient absorption Therefore it would be obvious to one of ordinary skill in the art to modify the method of Shapiro so as to add the step of ending pumping when the monitored volume exceeds preset parameters within a given time.

(Ans. 5.)

Principles of Law

“As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Analysis

Claim 17

Shapiro teaches a method of sham feeding in which a tube is inserted into the upper digestive system of an animal and the distal

portion of the tube extends outside the patient to a syringe (FF 2-4). Shapiro further teaches removing food from the upper digestive system (FF 4-5).

The Examiner acknowledges, however, that “Shapiro does not explicitly teach monitoring a volume of the pumped food” (Ans. 5). The Examiner further acknowledges that “Shapiro also does not explicitly teach ending the pumping when the monitored volume exceeds preset parameters within a given time” (*id.*).

However, Shapiro does provide evidence that the person of ordinary skill knows to use “controlled amounts and concentrations of liquids into the mouth” (Shapiro 131; FF 6). The Examiner also found that the ordinary artisan would recognize that monitoring the volume of pumped food and ending pumping at a present parameter would have been obvious in a sham feeding experiment in order to ensure that sham feeding had, in fact, occurred (FF 8, 9). As the Examiner found, the ordinary scientist involved in sham feeding experimentation would have “monitored volume of food required to prevent nutrient absorption” (Ans. 5). This is consistent with Shapiro’s teaching that animals involved in sham feeding increase meal size (*see* FF 7). Whether the increased meal size is measured by “monitoring a volume of the pumped food” as required by claim 17 or by measuring the amount of food remaining after feeding, Shapiro is further teaching that ordinary scientists routinely quantitatively monitor measurable aspects of an experiment (FF 6-7).

Appellants contend that

[A] person following the teachings of Shapiro would not be motivated to end the pumping after a certain volume has been pumped out within a given time. Instead, a person following the teachings of Shapiro would be motivated to continue pumping until as much food as possible has been removed.

(Reply Br. 7.) However, Appellants' claim 17 states "ending the pumping when the monitored volume exceeds preset parameters within a given time" (Claim 17). One reasonable parameter, and perhaps the most obvious parameter to preset based on Shapiro, would be a volume equal to the entire amount of food being fed, so "that the animal eats or drinks without receiving nutritional benefits" (Shapiro 125; FF 5). Consequently, Appellants' contention dovetails with the most obvious parameter that would have been suggested by Shapiro, which is monitoring the pumping to remove all of the food and/or drink as the preset parameter.

Appellants also contend that "'to establish a prima facie obviousness of a claimed invention, all the claim limitation must be taught or suggested by the prior art'" (App. Br. 10, emphasis in original). However, "a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 127 S. Ct. at 1741. Similarly, in the context of the patent examination process, the Examiner found that the person of ordinary skill would have monitored the volume of pumped food and ended the pumping based upon that monitoring (FF 8-9). As discussed above, the ordinary scientist routinely measures routine

variables and acts based upon these measurements as shown by Shapiro (FF 6-7).

Claims 32-34

Shapiro teaches a method of sham feeding in which a tube is inserted into the upper digestive system of an animal and the distal portion of the tube extends outside the patient to a syringe (FF 2-4). Shapiro further teaches removing food from the upper digestive system (FF 4-5). Shapiro expressly teaches that “[a]ny intervention at any level that *decreases* food intake is a potential model of anorexia but also a treatment of obesity and bulimia (Shapiro 117; FF 1).

Appellants contend that “the cited portions of Shapiro do not deal with treating bulimia – they deal with modeling or ‘mimicking bulimia’” (App. Br. 10). In fact, Shapiro expressly suggests that “[a]ny intervention at any level that *decreases* food intake is a potential model of anorexia but also a treatment of obesity and bulimia” (Shapiro 117; FF 1). This suggestion not only recognizes the relationship of obesity and bulimia, but also directly suggests that interventions which result in reducing nutrition function as treatments for obesity. Shapiro further recognizes that sham feeding is an intervention which reduces nutrition (FF 5, 7). Given these two teachings of Shapiro, the ordinary practitioner would have recognized that sham feeding is an obvious treatment for obesity.

Appellants further contend that “it would not be obvious to modify the method of Shapiro to treat obese patients because there is no suggestion or teaching in Shapiro of using any of the animal models for treatment of eating disorders” (App. Br. 10-11). As discussed immediately above, Shapiro includes a direct suggestion that an animal model may serve as a treatment (FF 1).

Appellants also contend that Appellants “understanding of Shapiro is that the author is critiquing the use of animal models in eating disorder research” (App. Br. 11). This argument implicitly suggests that the test subjects, such as rats or dogs, are not patients (*see* Shapiro 125-126 “Sham feeding has been used on various species, notably dogs, monkeys, rabbits, and rats.”). However, Appellants’ Specification imposes no limit on the species of “patient” and patients could encompass dogs or rats as tested by Shapiro. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.”).

Additionally, Shapiro recognizes that “psychologists used nonhuman animals to work out what were, in their view, the basic governing principles of all learning . . . these learning theories gave rise to several therapeutic techniques” (Shapiro 176). Thus, Shapiro is more nuanced than simply critiquing animal research. The Federal Circuit notes “[w]e will not read into a reference a teaching away from a process where no such language exists.”

DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1364 (Fed. Cir. 2006). There is no language in Shapiro which teaches away from the use of Shapiro's sham feeding model as a treatment for obesity and there is a direct suggestion that models can function as treatment modalities (FF 1).

Appellants also rely on *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005), contending that "the fact that the method steps of claims 32-34 positively recite that the patient is obese is significant." (App. Br. 11.) We agree with Appellants' claim interpretation analysis that patient obesity is a limitation in the claims, but disagree regarding the ultimate conclusion of obviousness. Claims 32-34 clearly recite, throughout the steps, application of the methods to an obese patient. However, as the Examiner found "Shapiro links obesity and bulimia and certainly fairly suggests the use of the sham feeding method to treat obesity" (Ans. 11). The ordinary practitioner is taught by Shapiro that "[a]ny intervention at any level that *decreases* food intake is . . . a treatment of obesity" (Shapiro 117; FF 1). Additionally, the ordinary practitioner is taught by Shapiro that "[f]istulae are utilized in sham feeding in such a way that the animal eats or drinks without receiving nutritional benefits" (Shapiro 125; FF 5). These teachings link obesity and sham feeding, reasonably suggesting to the ordinary practitioner that sham feeding is a predictable method for obesity treatment.

Conclusions of Law

The Examiner did not err in finding that it would have been obvious to an ordinary practitioner to monitor the volume of pumped food in Shapiro.

The Examiner did not err in finding that the treatment of obesity in claims 32-34 would have been obvious over the teachings of Shapiro.

SUMMARY

In summary, we affirm the rejection of claims 17, 18, and 32-34 under 35 U.S.C. § 103(a) over Shapiro.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

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